Office Action Summary	Application No. 08/468,145	Applicant(s) Engel
	Examiner Benet Prickril	Group Art Unit 1817

☒ Responsive to communication(s) filed on *Nov 7, 1996* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-11* is/are pending in the application.

Of the above, claim(s) *9 and 10* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-8 and 11* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☒ received in Application No. (Series Code/Serial Number) *08/198,037* .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *5*

☒ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Part III DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-8 and 11, drawn to pharmaceutical compositions and methods of making a peptide lyophilizate, classified in class 530, subclass 300.

   II. Claim 9, drawn to a method of treating female infertility, class 514 subclass 14, for example

   III. Claim 10, drawn to a method of providing male gonad protection, classified in class 514, subclass 14, for example.

Inventions I and II or III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptide lyophilizate product as claimed can be used in a materially different process such as use as a peptide molecular weight standard in biochemical assays.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they

have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as being capable of use together.

During a telephone conversation with Thomas Wiseman on October 30, 1996 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-8 and 11. Affirmation of this election must be made by applicant in responding to this Office action. Claims 9 and 10 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Claim Rejections

Claims 1, 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 recites dissolving a peptide in a sufficient amount of acetic acid to form a solution followed by transferring the solution to water. It is unclear whether a "sufficient

amount" is limiting with respect to the concentration of acetic acid used, or whether the acetic acid solution itself is aqueous prior to transferral to water.

Claims 7 and 8 are drawn to a pharmaceutical composition. A composition normally contains at least 2 components, yet the claims recite only the presence of a peptide. It is unclear what other constituents, if any, are present in the claimed composition.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 and 11 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Callahan et al. [US 4,908,475]. Callahan et al. teaches solubilization of a heptapeptide in approximately 100 - 10,000 parts by weight of acetic acid for each part of peptide wherein the peptide is subsequently transferred to water followed by lyophilization. The method of Callahan therefore meets every limitation of applicant's claims. See col. 13 lines 8-13.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Callahan et al. [US 4,908,475] in view of European Patent No. EP 88-308573, and further in view of Reissman et al. [*J. Cancer Res. Clin. Oncology, **118***, 44-49], Moore [US 4,711,877],

Yoshikawa et al. [US 5,268,360], Brown et al. [US 4,372,884], Stewart et al. [US 4,693,993], or Kornreich et al. [US 4,701,499].

Callahan et al. teaches solubilization of a heptapeptide in approximately 100 - 10,000 parts by weight of acetic acid for each part of peptide wherein the peptide is subsequently transferred to water followed by lyophilization. Finkenaur teaches a method of lyophilizing a decapeptide in the presence of the bulking agent mannitol. Reissman et al. discloses use of cetrorelix in a pharmaceutical composition. Moore (e.g., col. 8., lines 18-20), Yoshikawa et al. (col. 11, l. 54-57), Brown et al. (col. 5, l. 24-30), Stewart et al. (col. 7, l. 5-18), and Kornreich et al. (col. 4, l. 31-33) are cited because they teach the conventionality in the art of lyophilizing peptides of 3-15 amino acids after solubilization in a sufficient amount of acetic acid to form a solution. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate into the method of Callahan et al. addition of the bulking agent mannitol as taught by Finkenaur in order to make a lyophilizate of cetrorelix as taught by Reissman et al. In light of the conventional nature of lyophilizing small peptides in the range of 3-15 amino acids from acetic acid as taught, for example, by Moore, Yoshikawa et al., Brown et al., Stewart et al., and Kornreich et al., it would also have been obvious to carry out the lyophilization of other art recognized peptides such as Bombesin-Antagonist, Protirelin, or Somatostatin by the method of Callahan et al. in order to obtain applicant's invention. Motivation to combine the prior art teachings to arrive at applicant's invention is provided by the expectation in the art that

solubilization of peptides after dissolution in acetic acid will result in stabilization of the peptide, and therefore greater usefullness in pharmaceutical applications.

5. No claims are allowed.

General information regarding further correspondence

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1817.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benet Prickril, Ph.D., whose telephone number is (703) 305-5933. The examiner normally can be reached Monday through Thursday between 7:30 AM and 5:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, Ph.D., can be reached at (703)308-4310. The fax phone number for Art Unit 1817 is (703) 305-7939.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Benet Prickril, Ph.D.
January 9, 1997

PAULA K. HUTZELL
SUPERVISORY PATENT EXAMINER
GROUP 1800